REMARKS

Reconsideration of this application is respectfully requested.

Claims 31-47 are pending in the application, Upon entry of this Amendment, claims 32 and 33 will be canceled and claims 31, 34 and 37 will be amended.

The Examiner is thanked for indicating in the outstanding Office Action of May 20, 2004 that claims 39-42 and 44-47 are allowed. Accordingly, no further comments regarding these claims will be made in this Amendment.

The Examiner is also thanked for indicating that objected-to claims 37, 38 and 43 would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claims. Claim 37 has now been amended to place it in independent form, and, as such, such claim and dependent claims 38 and 43, which depend from claim 37, should now be in condition for allowance. Accordingly, no further comments regarding claims 37, 38 and 43 will be made in this Amendment.

In the outstanding Office Action, the Examiner rejected claims 31-36 under 35 U.S.C. §102(b) as being anticipated by Edwards *et al.* (USP 6,077,257). The Examiner also rejected claim 32 under 35 U.S.C. §103(a) as being unpatentable over Edwards in view of Mueller *et al.*, (USP 5,041,089), Sharkey *et al.* (USP 6,461,357), Baker *et al.* (USP 6,149,620) or Arenberg *et al.* (USP 5,419,321). The Examiner's rejections are respectfully traversed.

For a claim to be anticipated by a reference, each and every element recited in the claim must be present in the cited reference. In the present application, independent claims 31 and 34 each recite an active tissue treatment electrode

connected to a first generator output terminal and a return electrode connected to a second generator output terminal. Claims 31 and 34 have also been amended to clarify that both the active tissue treatment electrode and the return electrode are positioned in the space in the colon containing the tumour to be treated. Because Edwards *et al.* fail to disclose both active and return electrodes in connection with their tissue ablation apparatus, much less active and return electrodes that are positioned in the space containing the tissue to be ablated, the Edwards *et al.* reference does not anticipate independent claims 31 and 34.

In the outstanding Office Action of May 20, 2004, the Examiner, in his rejection of claims 31 and 34 under §102(b), identifies electrode 113 both as the active tissue treatment electrode and as the return electrode in the Edwards *et al.* device. As shown in Figure 1A of Edwards *et al.*, however, each electrode 113 which engages tissue to be ablated is not comprised of two different types of electrodes, such that catheter 110 can be said to be a bipolar device. Rather, as shown in Figure 1A, each electrode 113 is a single electrode, which includes a single metallic tube 114 defining a hollow lumen 115 that is shaped similarly to an injection needle, so as to be disposed to deliver "at least one flowable substance" to a region 140 near catheter 110. *Edwards et al.,* col. 3, lns. 50-53. Nowhere do Edwards *et al.* describe their catheter device 110 as a bipolar device including an active and return electrode positioned in the space in the colon containing the tissue to be ablated. If anything, Edwards *et al.*'s catheter device 110 is a monopolar device requiring a return, such as a patient ground pad, located outside

the space containing the tissue to be ablated to complete the electrical circuit for the operation of such device.

Thus, electrode 113 is not both the active and return electrodes recited in independent claims 31 and 34, such claims are not anticipated by Edwards *et al.* And because the remaining rejected claims 33, 35 and 36 depend from independent claim 31, they are also not anticipated by Edwards.

With regard to the Examiner's rejection of claim 32 under §103(a), claim 32 has now been canceled, and independent claims 31 and 34 have been amended to clarify that the active electrode in the claimed device is manipulated to vaporise the tumour to be treated. Contrary to the Examiner's arguments that ablation and vaporisation are equivalent and that it would have been obvious to use the Edwards *et al.* device to vaporise tumours, such a conclusion would ignore and, indeed, be directly contrary to the teachings of the Edwards *et al.* reference.

As noted in the Rule 132 Declaration of Colin Goble, the Director of Engineering at Gyrus Medical Ltd., the Assignee of this application, in the field of electrosurgery, there are two different types of tissue treatments, *i.e.*, "vaporization" and "lesion generation". As Mr. Goble explains in his Declaration, vaporization is the instantaneous removal of tissue, which involves the destruction of cells, and which is usually carried out at high temperatures, often in excess of 300° C. As Mr. Goble also explains in his Declaration, lesion generation is a process in which an electrosurgical electrode is brought into contact with tissue to cause cell necrosis, while leaving the tissue *in situ*, such that the dead cells are absorbed by the body over the course of subsequent days

or weeks. Mr. Goble further explains that, typically, this process is carried out at lower temperatures between 85° C and 120° C.

Clearly, Edwards *et al.* teach lesion generation, and not tissue vaporization. At column 8, lines 28-31, Edwards *et al.* teach the heating of tissue or other body structures by RF energy, "causing ablation by means of cell death, dehydration, or denaturation." In this same column, Edwards *et al.* also teach maintaining the temperature of the body structure to be ablated at a selected temperature between about 90° C and 120° C. Edwards *et al.*, col. 8, lns. 43-46. Indeed, Edwards *et al.* also teach the use of a microprocessor and a temperature sensor 119 to maintain the temperature of the body structure to be ablated within this selected temperature range. *See*, Edwards *et al.*, col. 8, lns. 39-46. To suggest that one skilled in the art would use the Edwards *et al.* ablation apparatus to vaporize tissue would require one to ignore and, more importantly, contradict the teachings of Edwards *et al.* and allow the operating temperature to go above the specified upper limit of 120° C. Thus, it would not be obvious to use the Edwards *et al.* ablation apparatus for vaporization, as recited in amended independent claims 31 and 34. As such, such claims are also not obvious over the teachings of the Edwards *et al.* reference.

In view of the foregoing, it is now believed that all of the claims remaining in the application, *i.e.*, claims 31 and 34-47, are now in condition for allowance, which action

is earnestly solicited. If any issues remain in this application, the Examiner is urged to contacted the undersigned at the telephone number listed below.

Respectfully submitted,

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